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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,656	08/28/2001	Arthur E. Uber III	P 265228 VI/98-013.FWC.C.	5530

21140 7590 03/09/2006

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EXAMINER	
DESANTO, MATTHEW F	
ART UNIT	**PAPER NUMBER**
3763	

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/939,656	UBER, ARTHUR E.	
	Examiner	Art Unit	
	Matthew F. DeSanto	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/15/05*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-18,63-65,67-78,80-88,90 and 91* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-18,63-65,67-78,80-88,90 and 91* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/10/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 13-18, 63-65, 67-78, 80-88, 90 and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson et al. (USPN 4,710,166), and further in view of Wortich (USPN 4,750,643) and Kampfe.

Thompson et al. discloses an injection device with a first fluid source and a second fluid source, as well as a mixing device (static and Y-connector), a pump or metering device, a control unit, valves and an electronic interface. (See Figures 1, and 11), but fails to disclose a fluid assurance device and multiple reusable and disposable portions.

Kampfe et al. discloses an injection device with a first fluid source (12), a second fluid source (14), a fluid path (16, 22, 24), and a mixing device (20); as well as a metering device (26,28,30), a control unit (42), and a fluid assurance device (60,62) (Figure 1 and entire reference). As well as wherein one of the sources is a contrast source and wherein one of the sources is a diluents source (column 8, line 61 - column 9, line 65).

Wortich discloses a sterile fluid dispensing system that comprises a fluid source, a fluid assurance element, multiple disposable portions, and a reusable flow path. (Figure 1 and entire reference)

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine Thompson et al. with Wortich because Wortich teaches the economic benefit of using the setup disclosed by Wortich as well as the ability to infuse fluid into multiple patients. Kampfe is used to show the level of skill in the art with regards to using contrast agents for medical treatment and that using a contrasting agent and diluted agent is well known in medical treatment, therefore making an obvious modification. The examiner would also like to note, that the step of removing the portion that is inserted into the patient or making that portion disposable is well known in the art because of the possibility of infection and contamination that can be transferred from one patient to another. Therefore, every medical device that injects fluid into a patient has to have a way to sterilize the element that is inserted into the patient. One well-known method is to use disposable elements that will be inserted into each new patient. Therefore, it is well known to replace each medical device that will be inserted into the patient.

The examiner would also like to note that the multiplication of the infuse lines is a mere duplication of parts and has been indicated by the courts as taking only routine skill in the art, which would further support the 103 Rejections made above.

3. Claims 13-18, 63-65, 67-78, 80-88, 90 and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orkin et al. (USPN 4,925,444) in view of Wortich (USPN 4,750,643) and Kampfe.

Orkin et al. discloses an injection device with a first fluid source and a second fluid source, as well as a mixing device, a pump or metering device, a control unit, valves and an electronic interface, a fluid assurance element and one reusable portion and a disposable flow path, (Figure 1 and entire reference), but fails to discloses multiple reusable and disposable portions.

Kampfe et al. discloses an injection device with a first fluid source (12), a second fluid source (14), a fluid path (16, 22, 24), and a mixing device (20); as well as a metering device (26,28,30), a control unit (42), and a fluid assurance device (60,62) (Figure 1 and entire reference). As well as wherein one of the sources is a contrast source and wherein one of the sources is a diluents source (column 8, line 61 - column 9, line 65).

Wortich discloses a sterile fluid dispensing system that comprises a fluid source, a fluid assurance element, multiple disposable portions, and a reusable flow path. (Figure 1 and entire reference)

At the time of the invention it would have been obvious for one of ordinary skill in the art to modify Orkin et al. because Wortich teaches the economic benefit of using the setup disclosed by Wortich as well as the ability to infuse fluid into multiple patients. Kampfe is used to show the level of skill in the art with regards to using contrast agents for medical treatment and that using a contrasting agent and diluted agent is well known

in medical treatment, therefore making an obvious modification. The examiner would also like to note, that the step of removing the portion that is inserted into the patient or making that portion disposable is well known in the art because of the possibility of infection and contamination that can be transferred from one patient to another. Therefore, every medical device that injects fluid into a patient has to have a way to sterilize the element that is inserted into the patient. One well-known method is to use disposable elements that will be inserted into each new patient. Therefore, it is well known to replace each medical device that will be inserted into the patient.

The examiner would also like to note that the multiplication of the infuse lines is a mere duplication of parts and has been indicated by the courts as taking only routine skill in the art, which would further support the 103 Rejections made above.

4. Claims 13-18, 63-65, 67-78, 80-88, 90 and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kerns et al. (USPN 4,756,706) and further in view of Kampfe et al. and further in view of Wortich.

Kerns et al. discloses an injection device with a first fluid source and a second fluid source, as well as a mixing device, a pump or metering device, a control unit, valves and an electronic interface, a fluid assurance element and one reusable portion and a disposable flow path, but fails to specifically describe multiple disposable portions as well as the different types of fluid that can be injected into a patient.

Kampfe et al. discloses an injection device with a first fluid source (12), a second fluid source (14), a fluid path (16, 22, 24), and a mixing device (20); as well as a

metering device (26,28,30), a control unit (42), and a fluid assurance device (60,62) (Figure 1 and entire reference). As well as wherein one of the sources is a contrast source and wherein one of the sources is a diluents source (column 8, line 61 - column 9, line 65).

Wortich discloses a sterile fluid dispensing system that comprises a fluid source, a fluid assurance element, multiple disposable portions, and a reusable flow path. (Figure 1 and entire reference)

At the time of the invention it would have been obvious for one of ordinary skill in the art to modify Kerns et al. in view of Kampfe and Wortich because Kampfe shows that a contrasting agent can be used for injection into a patient for treatment and Wortich teaches the economic benefit of using the setup disclosed by Wortich as well as the ability to infuse fluid into multiple patients. Therefore Kampfe shows that using contrast agents are an obvious modification in the medical treatment art. The examiner would also like to note, that the step of removing the portion that is inserted into the patient or making that portion disposable is well known in the art because of the possibility of infection and contamination that can be transferred from one patient to another. Therefore, every medical device that injects fluid into a patient has to have a way to sterilize the element that is inserted into the patient. One well-known method is to use disposable elements that will be inserted into each new patient. Therefore, it is well known to replace each medical device that will be inserted into the patient.

The examiner would also like to note that the multiplication of the infuse lines is a mere duplication of parts and has been indicated by the courts as taking only routine skill in the art, which would further support the 103 Rejections made above.

Response to Arguments

5. Applicant's arguments with respect to claims 13-18, 63-65, 67-78, 80-88, 90, 91 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F. DeSanto whose telephone number is 571-272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew DeSanto
Art Unit 3763
October 31, 2005